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Re-evaluation Note REV2014-04

Special Review Decision: Aminopyralid

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Special Review Decision

Aminopyralid is a herbicide, currently registered for use in Canada for the control of broadleaved weeds and woody plants in rangeland, pasture, industrial and other non-crop areas, as well as broadleaved weeds in wheat in the brown soil zone region of western Canada. Currently, 11 pest control products containing aminopyralid are registered in Canada under the authority of the *Pest Control Products Act*, including one technical grade active ingredient and ten commercial class end-use products. All registered pest control products containing aminopyralid were considered under this special review.

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) initiated a special review of all registered pest control products containing aminopyralid based on the 2011 Norwegian decision to prohibit all uses of aminopyralid in Norway due to environmental concerns. Based on the review of the Norwegian decision, the PMRA defined the aspect of concern that prompted the special review of aminopyralid as the potential for aminopyralid to leach to groundwater. Following the initiation of the special review, the PMRA requested information from all provinces and other relevant federal government departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*.

The PMRA assessed the potential leaching of aminopyralid to groundwater, and the potential drinking water risk from exposure to aminopyralid through groundwater. An evaluation of available relevant scientific information related to the aspect of concern that prompted the special review of aminopyralid indicated that pest control products containing aminopyralid do not pose unacceptable risks to human health or the environment when used according to the conditions of registration. Therefore, the PMRA, under the authority of the *Pest Control Products Act*, is confirming the current registration of all pest control products containing the active ingredient aminopyralid for sale and use in Canada.

This special review decision[1] was proposed in the consultation document[2] Re-evaluation Note REV2014-01, *Special Review of Aminopyralid: Proposed Decision for Consultation*, which outlines the Agency's proposed decision and the reasons for it. Comments received during the consultation process were taken into consideration in making this special review decision, and they did not result in changes to the proposed regulatory decision as described in REV2014-01. Appendix I summarizes the comments received during the consultation period and provides the PMRA's response to these comments. Please refer to REV2014-01 for more information on the PMRA's special review of aminopyralid. Regulatory Directive DIR2014-01, Approach to Special Reviews, presents the details of the PMRA's special review approach.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Other Information

Any person may file a notice of objection[3] regarding this decision on aminopyralid within 60 days from the date of publication of this special review decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website, Request a Reconsideration of Decision, or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

The PMRA received comments from stakeholders in response to Re-evaluation Note REV2014-01, *Special Review of Aminopyralid: Proposed Decision for Consultation*. The PMRA consolidated and summarized the comments related to this special review and provides responses below.

The comments have been grouped as indicated below:

- Scope of the special review of aminopyralid
- Science evaluation
- Special review process

1.0 Scope of the Special Review of Aminopyralid

1.1 Comment on pest control products under special review

The PMRA is focussing its special review on the active ingredient aminopyralid and not on pest control products containing this active ingredient. Subsection 17(2) of the *Pest Control Products Act* specifies that a special review initiated under that provision on the basis of a prohibition of an active ingredient applies in relation to registered pest control products containing that active ingredient.

PMRA Response

Under the *Pest Control Products Act*, a special review of all registered pest control products containing the active ingredient in question is required. Therefore, as part of this special review, the PMRA considered all registered pest control products (technical and end-use products) containing aminopyralid. A list of all the 11 products under special review was provided in Appendix I of REV2014-01, and the special review decision is applicable for all registered products containing aminopyralid. While assessing the potential leaching to groundwater, the PMRA considers the environmental chemistry and fate information from laboratory, field and monitoring studies, and reviews the risk-reduction measures included on all product labels, related to the aspect of concern. While the laboratory studies in general are carried out with technical active ingredients, the field studies are conducted with end-use products containing the active ingredient under actual conditions of use in the field. Additionally, the monitoring data gives an indication of the fate of the active ingredient when used as a formulated product under actual use scenarios. As part of this special review, the PMRA determined that the labels of all currently registered end-use products containing aminopyralid include precautionary measures to minimize the potential leaching of aminopyralid to groundwater and contamination of aquatic systems.

1.2 Comments on pest control products containing more than one active ingredient

Many registered pest control products may contain more than one active ingredient, and certain products contain another active ingredient for which a special review has been initiated. For example, in the case of aminopyralid, the registered product Restore II herbicide also contains 2,4-D, which is presently under special review. Such pest control products may present health and environmental risks that are unique and distinct from the risks of active ingredients assessed in isolation, as a result of additive and/or synergistic effects.

PMRA Response

Toxicology data on the formulated products are taken into account to inform the hazard statements on the individual product labels. The PMRA also considers cumulative health effects of pest control products when a common mechanism of toxicity is identified with other pest control products. Health Canada's Science Policy Notice SPN2001-01, *Guidance for Identifying Pesticides that have a Common Mechanism of Toxicity for Human Health Risk Assessment*, describes the steps for identifying mechanisms of toxicity of pesticides that cause a common toxic effect, the types of data needed and their sources, how these data are to be used in reaching conclusions regarding commonality of mechanisms of toxicity, and the criteria Health Canada applies for categorizing pesticides for the purpose of cumulative risk assessments. For aminopyralid, no common mechanism of toxicity has been identified with other pest control products. Therefore, no cumulative risk assessment was conducted. During the special review of 2,4-D, the PMRA will assess all the registered pest control products containing 2,4-D, including the above mentioned product, Restore II herbicide.

1.3 Comment on information considered by the PMRA for the special review

The PMRA appears to be avoiding the statutory mechanism available for obtaining relevant and necessary information. Any statutory notices sent pursuant to subsection 18(2) of the *Pest Control Products Act* should be posted on the application pages for special review.

PMRA Response

Although not specified in REV2014-01, following the initiation of the special review, the PMRA requested information from all provinces and other relevant federal government departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*. For the purpose of improved transparency and clarity, the fact that the subsection 18(2) process has been followed will be included in the future proposed special review decision documents.

1.4 Comment on water monitoring information

The proposed decision states that no Canadian groundwater monitoring data on aminopyralid is available, but does not indicate any efforts on the part of either the PMRA or the registrant to obtain such data. The comment also indicated that the United States Environmental Protection Agency (USEPA) is planning a 12-month groundwater monitoring study to support its registration review of aminopyralid, and that a special review is an opportunity to obtain Canadian data on aminopyralid.

PMRA Response

For the special review of aminopyralid, the PMRA sought water monitoring information from Canadian and American monitoring sources. No Canadian water monitoring information was available for aminopyralid, and the available American monitoring information from the State of Montana (representative of Canadian ecoregion) was considered in the special review as referenced in REV2014-01. The PMRA had sufficient information to assess the potential leaching of aminopyralid to groundwater in Canada. The PMRA determined that exposure to pest control products containing aminopyralid through drinking water is not of concern under the current conditions of use based on a scientifically based risk assessment. As noted in response 2.1, the aggregate exposure to aminopyralid from food and drinking water, which is 0.3% to 1.0% of the acceptable daily intake of 0.5 mg/kg bw/day for all population subgroups, is below the level of concern. Therefore, no additional water monitoring information is required at this time, as part of the special review for the currently registered uses.

Based on the USEPA's preliminary problem formulation,[4] the estimated drinking water concentrations for groundwater and surface water were "well below the level of concern for human health" based on a 2010 drinking water assessment for aminopyralid. The USEPA's aminopyralid final work plan for registration review[5] includes a "prospective groundwater monitoring study" as a data requirement and the decision is expected in 2020.

1.5 Comment on the information considered by the PMRA for the special review

A special review conducted pursuant to subsection 17(2) of the *Pest Control Products Act* should give thorough consideration to the concerns leading to a prohibition on the use of the active ingredient in another country to assess whether the risk and value of the product are acceptable for continued registration in Canada. This could include obtaining and analyzing relevant data. It may also provide an opportunity to consider new information on emerging issues that may not have been available to or considered previously by the PMRA or the country with a prohibition in place. A special review conducted pursuant to subsection 17(2) should not merely rubber stamp a pre-existing regulatory decision.

PMRA Response

When a special review is initiated under subsection 17(2) (in other words, based on the prohibition of all uses of an active ingredient for health or environmental reasons in an Organisation for Economic Co-operation and Development (OECD) member country), the PMRA carries out an analysis of the OECD decision to identify the aspect(s) of concern related to the pest control products (in other words, the concern(s) that resulted in the prohibition of the active ingredient in the OECD country). For aminopyralid, the aspect of concern that prompted the special review was identified as the potential for aminopyralid to leach to groundwater. The aspect of concern is then evaluated as required under subsection 18(4) of the *Pest Control Products Act*.

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4 USEPA, 2014. Registration Review. Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Aminopyralid, Potassium salt of Aminopyralid, and Triisopropanolamine Salt of Aminopyralid. EPA-HQ-OPP-2013-0749-0011.

5 USEPA, 2014a. Aminopyralid Final Work Plan. EPA-HQ-OPP-2013-0749-0042.

In order to evaluate aminopyralid's potential for leaching to groundwater, the PMRA has considered available relevant scientific information, which includes information available from Norway on the leaching potential of aminopyralid, information considered for the registration of aminopyralid in Canada, as well as any relevant information obtained since registration (for example, groundwater monitoring data). Information considered for special review, including that from Norway, was referenced in REV2014-01. Based on this information, the PMRA assessed aminopyralid's fate in the environment, potential levels in groundwater using water modelling, as well as water monitoring information. In addition, the PMRA conducted a dietary risk assessment (considering the toxicity of aminopyralid and potential exposure levels in both food and groundwater) and determined that dietary exposure to aminopyralid in drinking water (and food) is not of concern. On the basis of this scientific risk assessment, the PMRA concluded that pest control products containing aminopyralid do not pose unacceptable risks to human health or the environment under the current conditions of use.

2.0 Science Evaluation

2.1 Comment on PMRA approach to drinking water assessment

Norwegian regulations state that no pesticide should contaminate drinking water in concentrations above 0.1 µg/L, and the use of aminopyralid pesticide in Canada is estimated to result in groundwater concentrations of 66.7 µg/L. The proposed decision explains that the PMRA drinking water assessment takes into account toxicity, as well as estimated concentrations in drinking water, and that higher concentrations of aminopyralid are considered acceptable because of its low toxicity at these concentrations. This approach ignores the cumulative and synergistic risks of multiple substances contaminating drinking water, combined with other pathways of exposure. The PMRA should evaluate the appropriateness of its approach to managing drinking water contamination risks and assess alternative approaches (such as the Norwegian model) in light of subsection 19(2)(b)(i) requirements to take into account aggregate exposure and cumulative effects.

PMRA Response

The PMRA considers cumulative health effects of pest control products when a common mechanism of toxicity is identified with other pest control products. See the response to comment 1.2 for additional details. For aminopyralid, no common mechanism of toxicity with other pest control products has been identified. Therefore, no cumulative health risk assessment was required for aminopyralid.

Aggregate exposure to pest control products, namely dietary exposure and exposure from non-occupational sources, was considered by the PMRA as part of the special review of aminopyralid. There are no residential uses of aminopyralid registered in Canada; therefore, aggregate exposure is expected to be limited to food and drinking water only. The aggregate exposure to aminopyralid from food and drinking water constitutes 0.3% to 1.0% of the acceptable daily intake of 0.5 mg/kg bw/day for all population subgroups, which is below the level of concern.

The Norwegian Drinking Water Regulations (Regulation No. 1372) set quality standards for drinking water in Norway including a threshold of 0.1 µg/L for any individual pesticide in water intended for human consumption. The 0.1 µg/L threshold is a legislated rather than risk-based value that applies to all pesticides regardless of their toxicity to humans. The PMRA follows a risk-based scientific approach in determining the risk to human health from pesticides in drinking water taking into account aggregate exposure and cumulative health effects, where applicable. This approach takes into consideration both the estimated level in drinking water sources and the toxicity of the pesticide. Based on the aggregate exposure and risk assessment to aminopyralid from food and drinking water, the PMRA concludes that there are no risks of concern from groundwater under the current conditions of use.

2.2 Comment on the PMRA risk assessment

The USEPA has identified effects from chronic exposure at dose levels of 500–1000 mg/kg bw/day, which are lower than those identified by the PMRA.[6]

PMRA Response

The aspect of concern for the special review of aminopyralid was identified as the potential for aminopyralid to leach to groundwater. To assess the risk from exposure through groundwater, the PMRA conducted a dietary (food and drinking water) risk assessment based on an acceptable daily intake of 0.5 mg/kg bw/day derived from a no observed adverse effect level (NOAEL) of 50 mg/kg bw/day from a combined two-year chronic toxicity and oncogenicity study in the rat. Thus, the NOAEL used to derive the acceptable daily intake is 10 to 20-fold lower (in other words, more conservative) than the dose levels reported in the above-referenced USEPA document.

2.3 Comment on the PMRA risk management

The proposed decision suggests that the potential for aminopyralid contamination of groundwater in Canada is minimized by "precautionary statements" and measures stated on the label of end-use products. These measures are significantly less protective than the ban implemented in Norway to address the same issue. At a minimum, the PMRA should assess enforcement/compliance with labelled risk reduction measures and the effectiveness of precautionary statements in reducing contamination to groundwater.

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6 Environmental Protection Agency. 2010. Federal Register. Vol. 75, No. xx. p. 17570.

PMRA Response

The PMRA determined that exposure to aminopyralid through drinking water is not of concern under the current conditions of use based on a scientifically based risk assessment. As noted in response 2.1, the aggregate exposure to aminopyralid from food and drinking water, which is 0.3% to 1.0% of the acceptable daily intake of 0.5 mg/kg bw/day for all population subgroups, is below the level of concern. The precautionary label statements along with other mitigation measures (for example, spray drift buffer zones) included on the product labels are intended to further reduce the potential risk to humans and the environment. In addition, the PMRA routinely conducts active prevention and monitoring programs across the regulated community and follows up on situations of reported or suspected pesticides misuse, working in partnership with our federal and provincial colleagues.

2.4 Comment on additional margin of safety

Clarification is required as to whether the additional margin of safety of 10 was applied in the PMRA's risk assessment as required under subsection 19(2)(b)(iii) of the *Pest Control Products Act*.

PMRA Response

For the assessment of aminopyralid, the developmental and reproductive effects that would trigger an additional safety factor were taken into consideration. The aminopyralid database contains the full complement of required studies including developmental studies in rats and rabbits, and a reproductive study in rats. There was no evidence of reproductive toxicity or increased susceptibility of fetuses or offspring compared to parental animals in the available studies. The acceptable daily intake of 0.5 mg/kg bw/day used for the dietary risk assessment (food and drinking water) was based on a NOAEL of 50 mg/kg bw/day derived from a combined two-year chronic toxicity and oncogenicity study in rats and an uncertainty factor of 100-fold (10-fold for intra-species variation and 10-fold for inter-species extrapolation).[7] The uncertainty factor of 100-fold is considered protective of any potential toxicity, as there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children. Therefore, an additional safety factor was not required.

2.5 Comment on persistence of aminopyralid

Clarification is required as to the persistence of aminopyralid. Regulatory Note REG2007-01, *Aminopyralid* states that aminopyralid meets the criteria for persistence in soil and water/sediment systems, whereas in REV2016-01, aminopyralid was characterized as non-persistent to slightly persistent in most soil and persistent in aquatic environments. Clarification is also required regarding the assessment of field dissipation and persistence. Persistence is a characteristic of the substance and material balance must be met in analysing persistence.

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7 Canada, 2007, Pest Management Regulatory Agency, REG 2007-01, *Aminopyralid*

PMRA Response

The PMRA's assessment included in REV2016-01 indicates that aminopyralid is classified as non-persistent to slightly persistent in most soils, but can be persistent in others. Persistence information from five soil types was considered for the assessment of aminopyralid. Four out of the five soil types studied indicated non- to slight-persistence (half-life of 6 - 59 days) and one soil indicated persistence (half-life of 330 - 533 days). Biotransformation studies indicated that mineralization to CO_2 is the major route of transformation. Field studies indicated that field dissipation was rapid (dissipation time, DT_{50} 9- 58 days). To identify Track 1 substances that are persistent, toxic and bioaccumulative under the Toxic Substances Management Policy, the PMRA considers the most conservative values as outlined in REG2007-01, whereas, REV2016-01 presents overall information on persistence. The use of conservative values for the identification of Track 1 substances is to reflect the elevated concerns associated with this group of substances.

The PMRA considers laboratory studies of biotransformation to assess persistence and terrestrial field studies to determine the field dissipation. Material balance is considered as part of the acceptability of biotransformation studies. The PMRA recognizes that dissipation of a pesticide can occur through transformation and/or transport and it is estimated through the DT_{50} values. The DT_{50} values from Canadian and American field trials using aminopyralid products ranged from 9- 58 days and the main routes of dissipation are expected to be due to leaching and mineralization (REV2016-01).

2.6 Comment on residues in compost

Recently, concerns have been raised about aminopyralid residue in compost and animal feed. The recently published USEPA Registration Review work plan indicates that effects of aminopyralid residues in compost will be considered by the Agency during the Registration Review. The PMRA should also examine this issue, during the special review of aminopyralid, as residues in compost may lead to groundwater contamination. In the context of the special review, the potential for groundwater contamination as a result of leaching in areas where contaminated compost has been applied to pastureland, in the case of animal feed, are particularly relevant.

PMRA's Response

The USEPA registration review lead work plan for aminopyralid[a] identifies "compost dissipation study"[b] as a data requirement. Based on the USEPA's preliminary problem formulation,[b] this data is needed to understand the potential risk to terrestrial plants from aminopyralid residues in compost. Therefore, based on the available information, the data requirement is not related to potential leaching concerns. Pursuant to subsection 18(4) of the *Pest Control Products Act*, the PMRA has evaluated the aspect of concern that prompted the special review of aminopyralid (in other words, potential leaching to groundwater). As part of the analysis, the PMRA considered water monitoring information from actual use conditions, which may include the use of compost containing residues of aminopyralid, if any.

2.0 Special Review Process

2.1 Comment on the posting of special review documents, information included on the PMRA's Public Registry website, and public engagement

The comment indicated that special reviews are not transparent or accessible to the public. In addition to the consultation section of the PMRA website, the proposed special review decisions should also be posted in the "Application Documents" section of the respective special review submission in the PMRA's Public Registry website. For special review submissions, listing the registration number and product names as "Confidential" in Public Registry is misleading as this information is not confidential for special review submissions. There is interest to know the PMRA's efforts to engage interested parties in the special review process. A clarification is sought whether the PMRA intends to adopt additional or revised public notification, engagement and consultation mechanisms, beyond the simple posting of a proposed decision for written comment.

PMRA's Response

The consultation documents are available electronically through various means including the consultation section of the Health Canada website, in the PMRA's public registry, or upon request through the Information service/call line (1-800-267-6315 or 613-736-3799; pmra.infoserv@hc-sc.gc.ca). A subscription to the Really Simple Syndication (RSS) feed would allow stakeholders to obtain links to new Pesticides and Pest Management information when it is posted online.

All registration numbers and product names considered in the special review are included in an appendix to the proposed special review consultation document (REV2011-01).

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a USEPA, 2011a. Aminopyralid Final Work Plan. DP# D382089-2011-07300-0002.

b USEPA, 2010. Registration Review: Preliminary Problem Formulation for Environmental Fate, Ecological Risk, Endangered Species, and Human Health Drinking Water Exposure Assessments for Aminopyralid, Potassium salt of Aminopyralid, and Triisopropanolamine Salt of Aminopyralid. DP# D382089-2011-07300-0001.

As the consultation document is available through several avenues as indicated above, the PMRA, at this time, is not planning additional engagement and consultation mechanisms targeted for special reviews. However, the PMRA encourages all interested parties to provide comments on proposed special review decisions (consultation documents), and these comments will be considered before making final regulatory decisions.

3.2 Comment on accessibility to previous regulatory documents

Previous regulatory decisions that are relevant to the special review are difficult to locate on the PMRA website. The PMRA is requested to provide a list of all related regulatory documents, including URLs, with the proposed decision and that these related documents are clearly posted in the list of decisions and updates on the Health Canada website.

PMRA Response

All regulatory decisions that formed the basis of the proposed special review decision are included as references in the REV2014-01. Regulatory documents that are no longer available on the Health Canada website can be obtained electronically upon request, as specified on the website.

3.3 Comment on the Registration of Aminopyralid

The proposed special review document states that aminopyralid was first registered in 2006. No record of this registration decision is available on the Health Canada website, and the Regulatory Note REG2007-01 suggests that aminopyralid was proposed for temporary registration in 2007. This Regulatory Note also specifies that following the review of additional information, the PMRA was to publish a proposed registration decision document for comments before proceeding with a final regulatory decision. No record of a proposed registration decision for public consultation was found on the website; however, a 2008 regulatory document regarding the conversion of the registration of aminopyralid from temporary to full registration was found. We are concerned that the PMRA may have made a final regulatory decision about the registration of aminopyralid without undertaking consultations required under the *Pest Control Products Act*.

PMRA Response

Aminopyralid was granted a temporary registration in February 2006 before the current *Pest Control Products Act* came into force. Consequently, the initial registration was not subject to the public consultation requirement under the current Act. However, as part of improving transparency, REG2007-01 was published in 2007 regarding the decision made under the former Act. The PMRA acknowledges the confusion this may have caused given the date of publication of the Regulatory Note.

3.4 Comment on initiating special reviews

The PMRA should develop a systematic approach to initiate a special review when a member country of the OECD prohibits all uses of an active ingredient for health or environmental reasons. It was noted that Norway's ban on aminopyralid took effect in January 2011, but the PMRA did not initiate the legally required special review until December 2013.

PMRA Response

The PMRA will continue to monitor the regulatory status in OECD member countries of products containing active ingredients registered in Canada. The PMRA seeks information through participation in international working group meetings such as the OECD and the Rotterdam Convention, as well as from the publicly available databases.